K120239

6. 510(k) Summary or 510(k) Statement

510(k) SUMMARY

AUG 24 2012

510(k) Owner	Midmark Corporation 60 Vista Drive Versailles, Ohio 45380-0286 TEL: 937-526-8249
Contact person	Robyn Scopis Regulatory Consultant to Midmark Corp. Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.422.3853 FAX: 949.552.2821 EMAIL: robyn@regulatoryspecialists.com
Date summary was prepared	August 22, 2012
Name of device	Elevance
Common Name	Dental Delivery Unit
Classification Name	Unit, Operative Dental
Regulation	872.6640
Product Code	EIA
Unmodified Device	Midmark Procenter Instrument Delivery System K003090

Description

The Elevance Delivery Unit includes components to deliver air, water, electrical power, and vacuum to dental handpieces and accessories. The controls are contained in a Doctor's Unit, an Assistant's Unit, and a Cuspidor. Additional parts include mount arms, console mount housing, and a junction box that houses a power supply and air/water regulators. Handpiece accessories or instruments can be added to the Unit, Midmark does not manufacture these accessories but, do provide means to connect them into the Unit. These include high and low speed pneumatic handpiece tubing, electric handpiece motors, scalers, intraoral cameras, curing lights, air/water syringe, and SE and HVE vacuum instruments.

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Intended Use

The Midmark Elevance Instrument Delivery System is intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory. The system is designed to deliver air, water, vacuum and low-voltage electricity to hand-held dental instruments.

Technological Characteristics

The Unmodified Device and the Elevance were compared in the following areas and found to have similar technological characteristics and to be equivalent:

- Indications for Use
- Function of Handpiece Accessories
- Performance of Handpiece Accessories

The Unmodified Device and the Elevance were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined to not have any impact on the safety or efficacy of the Elevance:

- Centrally located controls for instruments
- Touch Pad on the Control Settings
- Air and Water Adjustment made via proportional solenoid valves

The following non-clinical performance tests were conducted:

- Qualification Run evaluation to verify design
- EN 60601-1-2:2007 Part 1-2
- EN 61000-3-2:2006 +A1:2009 +A2:2009 Part 3-2
- EN 60601-1-2:2007 Part 1-2
- IEC 60601-1 Part 1
- ISO 7494-1:2004
- ISO 7494-2:2003

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the Elevance demonstrates substantial equivalence to the predicate as a Dental Delivery Unit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Midmark Corporation
C/O Ms. Robyn Scopis
Regulatory Consultant
Regulatory Specialists, Incorporated
1801 Edgecliff Drive
Fullerton, California 92831

AUG 24 2012

Re: K120239
Trade/Device Name: Elevance
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 15, 2012
Received: August 21, 2012

Dear Ms. Scopis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

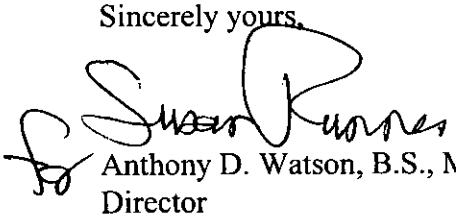
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120239

Indications for Use

510(k) Number (if known): TBD

Device Name: Elevance

Indications for Use:

The Elevance is intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory. The system is designed to deliver air, water, vacuum and low-voltage electricity to hand-held dental instruments.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

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